5. 510(K) SUMMARY OR 510(K) STATEMENT

K090986

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.
Date Prepared: 04/06/09

510(k) number: _____

DEC 30 2009

Applicant Information:
DFine Inc.
3047 Orchard Parkway
San Jose, CA 95134, USA

Contact Person
Sandeep Saboo
Phone Number: 408-321-9999 ext 248
Fax Number: 408-321-9401
e-mail: sandeeps@dfineinc.com

Device Information:

Trade Name:	StabiliT ER^x Bone Cement StabiliT Vertebral Augmentation System
Classification:	Class II (StabiliT ER^x Bone Cement) Class I (StabiliT Vertebral Augmentation System)
Classification Name:	Bone Cement Cement Dispenser

Physical Description:

StabiliT ER^x Bone Cement

The StabiliT ER^X Bone Cement is two-component PMMA bone cement with a powder component and a liquid component.

StabiliT Vertebral Augmentation System (for use with StabiliT ER^X Bone Cement)

StabiliT Vertebral Augmentation System is a motorized, microprocessor controlled bone cement delivery system intended for percutaneous delivery of bone cement in vertebroplasty or kyphoplasty procedures that allows for warming of the cement during cement delivery.

Intended Use:

StabiliT ER^X Bone Cement

The StabiliT ER^X Bone Cement is intended for the treatment of pathological fractures of the vertebrae using a vertebroplasty or kyphoplasty procedure. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

StabiliT Vertebral Augmentation System (for use with StabiliT ER^X Bone Cement)

The StabiliT Vertebral Augmentation System is intended for percutaneous delivery of StabiliT ER^X Bone Cement in vertebroplasty or kyphoplasty procedures in the treatment

of pathological fractures of the vertebrae. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

Test Results:

Performance

Results of in-vitro testing (material, performance, mechanical, electrical) demonstrate that the StabiliT ER^x Bone Cement and StabiliT Vertebral Augmentation System (for use with StabiliT ER^x Bone Cement) functioned as intended and the results of tests were as expected.

Biocompatibility

The materials used in the StabiliT ER^x Bone Cement and StabiliT Vertebral Augmentation System (StabiliT ER^X Bone Cement) meet the requirements of ISO 10993-1.

Substantial Equivalence and Summary:

The subject devices StabiliT ER^x Bone Cement and StabiliT Vertebral Augmentation System (for use with StabiliT ER^x Bone Cement) have the same intended use and indications, technological characteristics and principles of operation as their predicate, respectively, StabiliT ER Bone Cement (formerly known as SPACE CpsXL Bone Cement) [K072496] and SPACE 360 Delivery System (for use with SPACE CpsXL Bone Cement) [K070351] (also called StabiliT Vertebral Augmentation System).

The minor technological differences between StabiliT ER^x Bone Cement and StabiliT Vertebral Augmentation System (for use with StabiliT ER^x Bone Cement) and their predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that StabiliT ER^x Bone Cement and StabiliT Vertebral Augmentation System (for use with StabiliT ER^x Bone Cement) are as safe and effective as the predicate devices for their intended use. Thus, StabiliT ER^x Bone Cement and StabiliT Vertebral Augmentation System (for use with StabiliT ER^x Bone Cement) are substantially equivalent to their marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DFine Inc.
% Mr. Sandeep Saboo
3047 Orchard Parkway
San Jose, California 95134

DEC 30 2009

Re: K090986
Trade/Device Name: StabiliT ER^x Bone Cement and StabiliT Vertebral Augmentation System (for use with StabiliT ER^x Bone Cement)
Regulation Number: 21 CFR 888.3027
Regulation Name: Polmethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: NDN, KIH
Dated: December 17, 2009
Received: December 18, 2009

Dear Mr. Saboo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K090986

Device Name: StabiliT ER^X Bone Cement and StabiliT Vertebral Augmentation System (for use with StabiliT ER^X Bone Cement)

Indications for Use:

StabiliT ER^X Bone Cement:
The StabiliT ER^X Bone Cement is intended for the treatment of pathological fractures of the vertebrae using a vertebroplasty or kyphoplasty procedure. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

StabiliT Vertebral Augmentation System (for use with StabiliT ER^X Bone Cement):
The StabiliT Vertebral Augmentation System is intended for percutaneous delivery of StabiliT ER^X Bone Cement in vertebroplasty or kyphoplasty procedures in the treatment of pathological fractures of the vertebrae. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

Page __ of __

510(k) Number K090986